Application No.: 10/554,246

Attorney Docket No.: OKAD3006/REF/LES

LISTING AND AMENDMENT OF THE CLAIMS

1-19. (canceled)

20. (Currently Amended) A method for increasing <u>transgene transfer</u> efficiency expression in a gene transfer mediated by an adeno-associated virus vector (AAV), comprising:

administering (a) an AAV comprising a transgene and (b) an effective dose of a histone deacetylase inhibitor to a human subject in need thereof, wherein:

the histone deacetylase inhibitor is a compound represented by formula (I):

or a salt or a derivative of the compound; and

the effective dose of a histone deacetylase inhibitor is an amount that results in increased expression of the transgene—so that an episomal AAV genome, which has not undergone chromosomal integration, undergoes histone modification to enhance gene expression of the episomal AAV genome, wherein the histone deacetylase inhibitor is administered before administration of the adeno-associated virus vector.

21-23. (Canceled).

24. (Currently Amended) The method of claim 20,4 method of increasing gene transfer efficiency in a gene transfer mediated by an adeno-associated virus (AAV) vector, comprising:
administering an effective dose of a histone deacetylase inhibitor to a subject in need thereof wherein the histone deacetylase inhibitor is administered before administration of the adeno-associated virus vector.

25. (Canceled).

26. (Currently Amended) The method as described inof claim 20, wherein the subject is an adult and the effective dose of the histone deacetylase inhibitor is 1mg/m² to 50 mg/m² of a compound represented by formula (I):

or a salt or a derivative of the compound daily.

27. (Currently Amended) The method as described inof claim 20, wherein the gene transfer is performed AAV comprising a transgene and the histone deacetylase inhibitor are administered to tumor cells.

28-30. (Canceled).

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31. (Currently Amended) The method as described in claim 20of claim 27, wherein the method is performed for gene therapy, the gene transfer is performed to tumor cells and the subject has cancer.

- 32. (Currently Amended) The method-as described in claim 20claim 36, wherein, the gene transfer is performed the AAV comprising a transgene and the histone deacetylase inhibitor are administered to embryonic stem cells or hematopoietic stem cells.
- 33. (Currently Amended) The method as described inof claim 20, wherein the method is performed for gene therapy and the subject has <u>cancer</u>; a neuromuscular disease; myotonic dystrophy; amyotrophic lateral sclerosis (ALS); heart failure; cardiomyopathy; diseases treated with protein supplementation therapy through expression of a secretory protein; chronic systemic diseases; arteriosclerosis; hypertension; heart failure; diabetes; hyperlipidemia; cerebral infarction; reperfusion injury after cerebral ischemia; Parkinson's disease; various neurodegenerative disease; mitochondrial encephalomyopathy; epilepsy; schizophrenia; or alcoholism.

34-35. (Canceled).

36. (Currently Amended) A method for increasing the efficiency of a transduction mediated by an adeno-associated virus vector (AAV), comprising: administering (a) an AAV comprising a transgene and (b) an effective amount of a histone deacetylase inhibitor to human cells in need thereof, so that an episomal AAV nucleotide sequence, which has not undergone chromosomal integration, undergoes histone modification to enhance expression of the episomal AAV nucleotide sequence, wherein;

the histone deacetylase inhibitor is a compound represented by formula (I):

or a salt or a derivative of the compound; and

the effective dose of a histone deacetylase inhibitor is an amount that results in increased transduction efficiency; and

the histone deacetylase inhibitor is administered before administration of the adenoassociated virus vector.

- 37. (Original) The method as described in claim 36, wherein the cells are tumor cells of a subject.
- 38. (Original) The method as described in claim 36, wherein the histone deacetylase inhibitor is a compound represented by the formula (I):

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or a salt or a derivative of the compound.

39. (Currently Amended) The method according to claim 36, wherein the effective amount of a histone deacetylase inhibitor is administered simultaneously with, immediately before, or immediately after AAV-vector-mediated transduction,

wherein the cells are tumor cells of a subject, and

wherein the histone deacetylase inhibitor is a compound represented by the formula (I):

or a salt or a derivative of the compound.

40. (New) The method of claim 20, wherein the histone deacetylase inhibitor is FK228.

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- 41. (New) The method of claim 36, wherein the histone deacetylase inhibitor is FK228.
- 42. (New) The method of claim 20, wherein the derivative is obtained through acetylation of the compound or through reduction of the S-S bond of the compound.
- 43. (New) The method of claim 36, wherein the derivative is obtained through acetylation of the compound or through reduction of the S-S bond of the compound.